REMARKS

A. Status of the Claims

Claims 1-32 are currently pending and claims 33-40 are cancelled without prejudice. Applicants note that the Action, at paragraph 3, states that this is a Final Action (sic), and that claims 33-40 should be cancelled, since a complete reply to the final rejection must include cancellation of non-elected claims. However, the Office Action Summary page states that this is a non-final Action, which was confirmed in a telephone call with Examiner Robinson on September 17, 2008. Claims 1-32 are presented for reconsideration.

B. Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Definiteness

The Action rejects claims 1 and 15 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, it is asserted that the claims recite a mean whole seed protein content of between 45% and 50%, a mean whole seed oil content of at least 20%, and a mean whole seed total protein plus oil content of between 64% and 70%. Since the claimed individual percentages of oil and protein content do not add up to a total oil plus protein content of 64-70%, the claims are considered indefinite. Applicants respectfully traverse

Applicants respectfully submit that the claims are definite as they currently stand, because the limitations relating to protein content, oil content, and protein plus oil content, are linked by "and," and "65%" is between 64-70%. Thus one of ordinary skill in the art would be apprised of the scope of the claim. Withdrawal of the rejection is thus respectfully requested.

C. Claim Rejection Under 35 U.S.C. § 112, First Paragraph- Written Description

The Action maintains the rejection of claims 1-32 as failing to comply with the written description requirement for the reasons stated in the Action dated September 4, 2007. In particular, it is asserted that the Specification only provides evidence that Applicant was in

possession of soybean varieties 0007583, 0008079, 0137335, 0137472, 0137441, and 0137810 (*e.g.* pages 43-62 of the Specification), having the claimed characteristics wherein said plant is a progeny of soybean variety SN30003. The Action also asserts that the claims do not recite seed deposits, nor do they recite any structure in deposited seed that produces the claimed characteristics such as protein content, oil content, or commercially significant yield. Applicants respectfully traverse.

Applicants note that the claims were amended to recite "wherein the soybean plant is a progeny plant of soybean variety SN30003, or a subsequent generation thereof." Applicants have pointed out that soybean varieties 0007583, 0008079, 0137335, 0137472, 0137441, and 0137810 are all progeny of SN30003. Additionally, **line SN30003 is publicly released and available to the breeding community, as noted in Wilcox (*Crop Sci.* 38:900, 1998)**. Further, 37 CFR §1.802(b) states that "...Biological material need not be deposited...if it is known and readily available to the public." As such, a deposit of seed of variety SN30003 (*i.e.* C1944) is not believed to be required to comply with the Written Description Requirement.

Regarding composition claims, Applicants respectfully submit that the discussion in the previous response regarding soybean varieties that are progeny lines of SN30003, and the related seed deposits, is made in order to demonstrate possession of species (*e.g.* soybean variety 0007583) representing the claimed invention. M.P.E.P. 2163 I explicitly states, as noted previously, that "...Possession may be shown in a variety of ways...An application specification may show actual reduction to practice...or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801..." Thus the seed deposits of certain progeny of variety SN30003, such as line 0007583, are referenced to demonstrate actual reduction to practice of the compositions of the presently claimed invention. Further, "...a

patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, *e.g.*, *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Given that the soybean breeding line SN30003 (*i.e.* C1944) is known in the art and is publicly available, one skilled in the art could reasonably conclude at the filing date that the inventor had possession of the claimed invention, for instance, use of soybean line SN30003 in a breeding program to develop a soybean variety displaying the recited protein, oil, and yield levels. Further limiting the claims to lines such as those listed would not be commensurate with the inventors' contribution to the art.

Applicants also submit again that the Examiner has not met his initial burden to present evidence why the Written Description Requirement has not been met (*e.g.* Response of January 4, 2008, pages 12-13), and the current action does not address this issue. Given the teachings of the Specification, one or ordinary skill in the art of plant breeding would clearly be directed toward use of SN30003 in designing a soybean breeding program to create soybean varieties with the recited protein, oil, and yield characteristics. If the rejection is made in view of a lack of seed deposit of line SN30003, Applicants respectfully request that this be stated on the record, in accordance with M.P.E.P. 2411.01, including reasoning why such a seed deposit is needed given the text of 37 CFR §1.802(b).

The Action further asserts that "Applicant does not describe any structure in the deposited seed that produces the claimed characteristics such as protein content, oil content or commercially significant yield." In response, Applicants submit that no such "structures" are found in the claims, and a rejection made on that basis is thus unwarranted. Again, however,

Applicants respectfully request that the Examiner indicate whether a deposit of seeds of soybean variety SN30003 in accordance with 37 CFR 1.801 would be understood to satisfy the Written Description Requirement in this regard.

The Action also maintains the rejection of method claims 16-28 and independent method claims 30-32 in view of the Written Description Requirement, and does not address arguments made in previous responses, such as the response dated January 4, 2008 at pages 13 and following. Applicants again respectfully submit that the same reasoning of the written description rejection is not properly applied both **to claims relating to soybean plants** derived from line SN30003, **and also to claimed methods** for breeding soybean plants such as independent claims 30-32. The Action provides no indication that the recited steps of these claims are unclear, or that a skilled practitioner would find them to be unclear. Further, methods for determining protein, oil, and yield levels are well known and these claims have not been asserted to be unclear.

The development of soybean lines such as 0007583 (deposited as PTA-5764) clearly indicates actual reduction to practice- that the method has successfully been used to achieve the claimed result. Although the Action asserts that the starting materials used in the recited method steps are not adequately described (Action, page 6), Applicants again submit that line SN30003 (*i.e.* C1944) is clearly described in Wilcox (*Crop Sci.* 38:900, 1998), has been publicly available from the breeder or from the USDA as PI599584, and 37 CFR §1.802(b) states that biological material need not be deposited if it is known and readily available to the public. As noted above, Applicants also respectfully request that the Examiner indicate whether a deposit of seeds of soybean variety SN30003 in accordance with 37 CFR 1.801, *i.e.* the starting material used in the method steps, would be understood to satisfy the Written Description Requirement.

D. Claim Rejection Under 35 U.S.C. § 112, First Paragraph- Enablement

The Action maintains the rejection of claims 1-29 and 32 under 35 U.S.C. § 112, first paragraph, based on the assertion that the specification does not reasonably provide enablement for each and every progeny soybean plant of SN30003 having the claimed mean whole seed protein content, whole seed oil content, and mean whole seed total protein plus oil content, and a commercially significant yield. Also, the Action asserts that it would require undue trial and error experimentation to reproduce variety SN30003.

In response, Applicants note that the Specification provides sufficient disclosure to satisfy the enablement requirement of 35 U.S.C. § 112, First Paragraph, for this subject matter, in that the Specification provides working examples within the scope of the claims, and the teachings of the Specification combined with the knowledge of one of ordinary skill in the art provides sufficient guidance to practice the invention, both with respect to the product claims and the method claims. Applicants repeat that the assertion of the Action, that the Specification provides enablement for soybean varieties 0007583 and 0137441, among others, actually argues that at least the method claims are enabled, since products of the claimed methods were in the possession of the inventors.

Regarding both composition and method claims, and given the teachings of the Specification, one of ordinary skill in the art of plant breeding could create progeny plants of soybean line SN30003 and test them for yield, oil, and protein content using methods well known in the art. Indeed the Action of September 2007 acknowledges (at page 6) that Applicants' arguments were persuasive with regard to previously asserted "undue trial and error experimentation" as they pertain to screening soybean plants for the desired trait. Further, "reproduction" of line SN30003 is not required by the claims. Thus Applicants can discern no

explicit basis for maintaining the enablement rejection. *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."; see M.P.E.P. 2164). In order to advance prosecution, Applicants respectfully request that the Examiner indicate whether a deposit of seeds of soybean variety SN30003 in accordance with 37 CFR 1.801 would be understood to overcome the Enablement rejection. In view of the foregoing, withdrawal or clarification of the rejection is respectfully requested.

E. Claim Rejection Under 35 U.S.C. § 103(a)

The Action maintains the rejection of claims 1-32 under 35 U.S.C. § 103(a) as being unpatentable over Wilcox (*Crop Sci.* 38:900, 1998), in view of Conway (U.S. Patent No. 6,140,556). Applicants respectfully traverse.

The Action alleges that SN30003 could be crossed with another soybean cultivar to produce novel soybean cultivars. Thus the remaining issue is understood to be whether any such resulting novel soybean cultivars would have or would have been expected to have, at the filing date of the present application, the claimed characteristics (*i.e.* the claimed oil content, protein content, protein plus oil content, yield, and other elite agronomic characteristics).

The pending Action does not indicate how the cited Wilcox reference (*Crop Sci.* 38:900, 1998), in combination with Conway, renders the claimed invention obvious. As an initial matter, Applicants respectfully submit that the Wilcox reference (*Crop Sci.* 38:900, 1998) does not describe C1944 as an agronomically elite soybean plant. Instead, Wilcox only states that this line may be useful for further breeding. Likewise, cited reference C44, a printout of information

relating to PI599584 from the USDA GRIN (National Plant Germplasm) Database, describes the improvement status of this line as "breeding material." Thus a plant breeder would not recognize that this is an agronomically elite soybean plant.

Further, although SN30003 might be used in a cross with a second variety that displays 20% seed oil content, a skilled soybean breeder simply would have had no expectation of success, *i.e.* that any resulting progeny plant line would display the claimed characteristics, such as the claimed levels of seed oil content, seed protein content, and seed oil plus seed protein content. This is because of the strong negative correlation between seed oil content and seed protein content as was previously discussed. The Wilcox reference notes that seed protein and oil content are negatively correlated when it states (page 900, left column) that "The lines will be useful for increasing seed protein content while minimizing reductions in seed oil content." But Wilcox provides no teaching that the claimed high levels of both protein and oil could be obtained in progeny, and Conway does not relate to breeding for high protein plus oil content. Applicants respectfully submit that the rejection is maintained without adequate reasoning or support.

Nowhere in Conway is there mentioned that negative correlation for instance between protein and oil content. Importantly, Conway teaches breeding to achieve the characteristics of the soybean cultivar designated CX414cRR, a herbicide resistant soybean line, but does not test this line for oil and protein content. Given that Conway does not address the difficulty of achieving the recited levels of oil, protein, oil + protein, and yield, the teachings of Conway are only of the most general nature, and do lead one of ordinary skill to have any expectation of success when breeding for a soybean plant that displays the recited characteristics relating to oil plus protein content. That is, the Action only asserts that novel cultivars might be produced,

without explaining how such novel cultivars might have been expected to demonstrate the specific claimed characteristics.

On the contrary, the art very clearly teaches away from the claimed result. In particular, the cited reference by Wilcox does not describe characteristics of progeny plants. Again, it only states that the lines of Wilcox might be useful in further breeding attempts that could "minimize" reductions in oil content without describing any actual resulting oil content, or oil plus protein content. This recognizes the difficulties in breeding for characteristics such as those presently claimed, and does not indicate that the claimed characteristics would have been expected to be achievable prior to the teachings of the present application. Applicants again note, as also detailed above, that there would have been no expectation that progeny of such a cross, in any subsequent generation, would have displayed the claimed characteristics, in particular the claimed levels of seed oil, seed protein, and seed protein plus seed oil. Thus a progeny plant that might, for instance, display an oil content of a >20% oil parent, would have been expected, for instance, to fail to display a high protein content, or yield, of the second parent.

Wilcox in view of Conway is at best an invitation to experiment further, but with no expectation of success, since neither reference contains teachings that would lead one of ordinary skill in the art of soybean breeding to expect that the claimed seed protein plus seed oil levels were achievable. Further, Wilcox and Cavins (*Crop Sci.* 35:1036, 1995, cited as reference C42) discuss the negative correlations between protein content, oil content, and yield in soybean breeding. At page 1040, right column, while discussing their Fig. 1, they note that "Deviations from regression of protein concentration on oil concentration were progressively smaller and R^2 values were progressively larger with successive backcrosses..." Thus, the inverse relationship between seed protein and seed oil content became stronger in successive generations of progeny.

Applicants also note that Wilcox and Cavins are describing a more than 20 year long soybean breeding project (at least approximately 1971-1992; see materials and methods) covering more than a dozen generations of crosses, backcrosses, and intercrosses, and yet were still unable to produce a high protein soybean cultivar displaying the oil content of the recurrent parent, Cutler 71, let alone displaying the presently claimed characteristics. Applicants submit that this is strong evidence in the art teaching away from the presently claimed invention. Applicants respectfully request that the Examiner point out any teachings in the art that would lead one of skill, as of the filing date, to expect that soybean lines derived from a cross using SN30003 as a parent would display these claimed characteristics. In the absence of such a showing withdrawal of the rejection is respectfully requested.

F. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (214) 259-0932 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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